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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,144	11/25/2003	Robert J. Ternansky	474930-4	9257
32940	7590	08/24/2005	34433/US/3/AMP/S	
DORSEY & WHITNEY LLP 555 CALIFORNIA STREET, SUITE 1000 SUITE 1000 SAN FRANCISCO, CA 94104			EXAMINER CORDERO GARCIA, MARCELA M	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/723,144

Applicant(s)

TERNANSKY ET AL.

Examiner

Marcela M. Cordero Garcia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6-17, 19-58 and 60-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 18 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

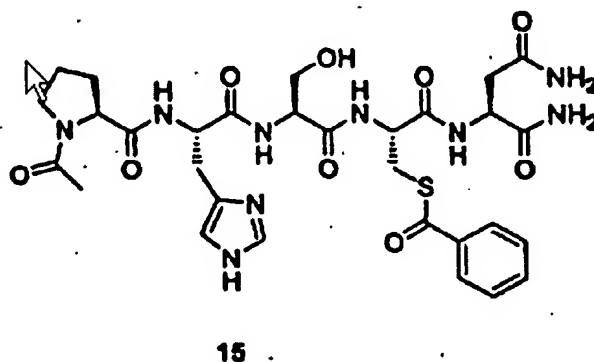
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/04</u> . | 6) <input type="checkbox"/> Other: _____  |

J. 00

### DETAILED ACTION

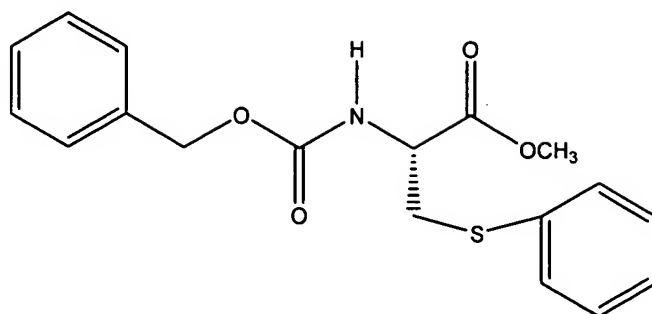
Applicant's election of Group I (claims 1-59) in the reply filed on May 31, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In addition, Applicant's election of the species of Formula I wherein R<sup>1</sup> is acyl (i.e., -C(O)CH<sub>3</sub>, x is 1, A is Pro, y is 1, B is His, z is 1, C is Ser, a is 1, R<sup>2</sup> is - (CH<sub>2</sub>)<sub>m</sub>S(O)<sub>n</sub>R<sup>5</sup>, m is 1, n is 0, R<sup>5</sup> is acyl (i.e., C(O)Ph), b is 1, R<sup>3</sup> is -CH<sub>2</sub>CONH<sub>2</sub>, R<sup>4</sup> is - NR<sup>6</sup>R<sup>7</sup> and R<sup>6</sup> and R<sup>7</sup> are hydrogen, as indicated in the following structure:



in the reply filed on May 31, 2005 is acknowledged, with claims 1-7, 20-22, 25, 30-31, 44 and 59 readable thereon. This species was searched and found to be free of the prior art.

Therefore, examiner elected another species from amongst those encompassed by the instant claims. The species is of Formula I, wherein a is 1, b = 0, x = 0, y = 0, z = 0, R<sup>2</sup> is -(CH<sub>2</sub>)<sub>m</sub>S(O)<sub>n</sub>R<sup>5</sup>, m = 1, n = 0, R<sup>5</sup> = aryl (Phe), R<sup>1</sup> is substituted oxycarbonyl (CO-O-Phe) and R<sup>4</sup> is -OR<sup>8</sup>, wherein R<sup>8</sup> is alkyl (Me), as follows:



Claims 1, 5, 18 and 59 read on the elected species.

Claims 2-4, 6-17, 19-58 are not drawn to the elected species and are therefore withdrawn from examination.

Claims 1, 5, 18 and 59 are presented for examination on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 18 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the proviso phrase "a is 1 unless A is proline, B is histidine, C is serine and b is 0 when a is 0;" because it is unclear if the statement "b is 0 when a is 0" is connected exclusively to the event when a is 0 and A is proline, B is histidine and C is serine. Please note that this proviso seems to contradict Applicant's elected species, wherein a is 1, A is proline, B is histidine, C is serine.

All other claims that depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 18 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (WO 98/30538).

Kondo et al. teach a compound of structural Formula (I) wherein a is 1, b = 0, x = 0, y = 0, z = 0, R<sup>2</sup> is  $-(CH_2)_mS(O)_nR^5$ , m = 1, n = 0, R<sup>5</sup> = aryl (Phe), R<sup>1</sup> is substituted oxycarbonyl (CO-O-Phe) and R<sup>4</sup> is  $-OR^8$ , wherein R<sup>8</sup> is alkyl (Me). (See, e.g., page 2).

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 18 and 59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-70 of copending Application No. 10/722,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention and the invention claimed in Application '843 are both drawn to peptide compounds of Formula (I) and Formula (V) respectively, which claim at least one or more overlapping species. Further, the instantly claimed product encompasses and/or is encompassed by the claimed product of Application '843.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Marcela M Cordero Garcia, Ph.D.  
Patent Examiner  
Art Unit 1654

MMCG 08/05

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER